

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SUN PHARMACEUTICAL INDUSTRIES,
INC. and MICAL PHARMACEUTICALS
LLC—H SERIES

Plaintiffs,

v.

PERRIGO COMPANY, PERRIGO ISRAEL
PHARMACEUTICALS LIMITED and
PERRIGO NEW YORK, INC.

Defendants.

C.A. No. _____

**PLAINTIFFS SUN PHARMACEUTICAL INDUSTRIES, INC. AND
MICAL PHARMACEUTICALS LLC—H SERIES COMPLAINT AGAINST
PERRIGO COMPANY, PERRIGO ISRAEL PHARMACEUTICALS LIMITED,
AND PERRIGO NEW YORK, INC.**

Plaintiffs Sun Pharmaceutical Industries, Inc. and MiCal Pharmaceuticals LLC—H Series (together, “Plaintiffs”) for its complaint against defendants, Perrigo Company, Perrigo Israel Pharmaceuticals Limited, and Perrigo New York, Inc. (collectively, “Perrigo” or “Defendants”), to the best of its knowledge, information and belief, allege as follows:

NATURE OF THE ACTION

1. This is an action under 35 U.S.C. § 271(e)(2) for infringement of United States Patent No. 8,962,028 (the “’028 Patent”) (attached as **Exhibit A**), and for declaratory judgment of infringement under 28 U.S.C. § 2201-02 and 35 U.S.C. § 271(a), (b), and (c) relating to Plaintiffs’ commercially successful product, Ultravate® (halobetasol propionate) Lotion, 0.05%. This action arises from Defendants’ filing of an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to market a generic

version of Ultravate[®] (halobetasol propionate) Lotion, 0.05% prior to the expiration of the '028 Patent.

THE PARTIES

2. Sun Pharmaceutical Industries, Inc. is a company organized and existing under the laws of the State of Michigan, with a principal place of business at 2 Independence Way, Princeton, New Jersey 08540.

3. MiCal Pharmaceuticals LLC—H Series, a Series of MiCal Pharmaceuticals LLC, a Multi-Division Limited Liability Company (“MiCal”), is a company organized and existing under the laws of the State of Delaware, with a principal place of business at 9025 Balboa Avenue, Suite 110, San Diego, CA 92123.

4. On information and belief, Defendant Perrigo Company is a corporation operating and existing under the laws of Michigan, having a principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010.

5. On information and belief, Defendant Perrigo Israel Pharmaceuticals Limited (“Perrigo Israel”) is a corporation operating and existing under the laws of Israel, having a principal place of business at 29 Lehi Street, Bnei Brak 51200, Israel.

6. On information and belief, Defendant Perrigo Israel is a wholly owned subsidiary of Perrigo Company.

7. On information and belief, Defendant Perrigo New York, Inc. is a corporation operating and existing under the laws of Delaware, having a principal place of business at 1700 Bathgate Avenue, Bronx, NY 10457.

8. On information and belief, Defendant Perrigo New York, Inc. is a wholly owned subsidiary of Perrigo Company.

9. On information and belief, Perrigo Israel and Perrigo New York, Inc. manufacture, sell, market, and distribute generic pharmaceutical products throughout the United States, including in this district, in conjunction with or under the direction of Perrigo Company. On information and belief, Perrigo Israel has designated Perrigo Company as its US agent for its ANDA submission.

10. On information and belief, Perrigo developed its generic halobetasol propionate lotion, 0.05%, and prepared ANDA No. 211464 for submission. On information and belief, upon receiving approval of its ANDA No. 211464, Perrigo will manufacture, sell, offer to sell, and/or import Perrigo's generic halobetasol propionate lotion, 0.05% in the United States, including in this district.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq.* and the Declaratory Judgement Act. Based on the facts alleged herein, this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201 and 2202, and has personal jurisdiction over Perrigo Company, Perrigo Israel, and Perrigo New York, Inc.

12. Perrigo Israel has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends to manufacture, use, sell, and offer for sale its proposed generic halobetasol propionate lotion, 0.05% in Delaware. On information and belief, Perrigo Company directed Perrigo Israel to participate and collaborate in the research and development of the proposed generic halobetasol propionate lotion, 0.05% and in the preparation and filing of ANDA No. 211464.

13. On information and belief, Perrigo sought FDA approval because it intends to commit acts of patent infringement under 35 U.S.C. § 271(a), (b), and (c) through its manufacture, use, sell, and offer for sale of its generic halobetasol propionate lotion, 0.05% in Delaware.

14. An actual and justiciable controversy exists between the parties under the patent laws of the United States, Title 35 of the United States Code.

15. This Court has personal jurisdiction over Perrigo. Perrigo avails itself of the benefits and protections of the laws of the State of Delaware. For example, Perrigo New York, Inc. is incorporated in the State of Delaware and is a manufacturer and wholesale distributor of pharmaceuticals.

16. This Court also has personal jurisdiction over Perrigo by virtue of its systematic and continuous contacts with the State of Delaware. On information and belief, Perrigo Company, Perrigo Israel, Perrigo New York, Inc. and their affiliates manufacture generic pharmaceuticals and sell, offer for sale, and distribute generic pharmaceuticals throughout the State of Delaware.

17. On information and belief, Perrigo has at all relevant times maintained continuous and systematic contacts with the State of Delaware, including but not limited to, its aforementioned business of preparing generic pharmaceuticals that Perrigo distributes throughout the United States.

18. On information and belief, Perrigo's generic halobetasol propionate lotion, 0.05% will be marketed and distributed in Delaware by Perrigo, prescribed by physicians practicing in this state, and dispensed by pharmacies located in this state, all of which would have a substantial effect on commerce.

19. Perrigo has previously availed themselves of the jurisdiction of this Court by filing suit in this district, consenting to jurisdiction in this district, and/or asserting counterclaims in at

least the following civil actions initiated in this district: *Leo Pharma A/S et al. v. Perrigo Uk Finco L.P. et al.*, 1:18-cv-401; *Perrigo Company v. International Vitamin Corp. et al.*, 1:17-cv-1778; *Leo Pharma A/S et al. v. Perrigo Uk Finco L.P. et al.*, 1:17-cv-1753; *Meda Pharmaceuticals Inc. et al. v. Perrigo Uk Finco L.P. et al.*, 1:16-cv-794; *Galderma Laboratories, L.P. et al. v. Perrigo Uk Finco L.P. et al.*, 1:16-cv-732; *Leo Pharma A/S et al. v. Perrigo Uk Finco L.P. et al.*, 1:16-cv-430; *Senju Pharmaceutical Co. Ltd. et al. v. Paddock Laboratories LLC et al.*, 1:15-cv-87; *Horizon Pharma Ireland Ltd. et al. v. Paddock Laboratories LLC et al.*, 1:15-cv-43; *Endo Pharmaceuticals Solutions Inc. et al. v. Custopharm Inc. et al.*, 1:14-cv-1422; *Unimed Pharmaceuticals LLC et al. v. Perrigo Company et al.*, 1:14-cv-1003; *Taro Pharmaceuticals USA Inc. et al. v. Perrigo Israel Pharmaceuticals Ltd.*, 1:14-cv-989; *Unimed Pharmaceuticals LLC et al. v. Perrigo Company et al.*, 1:14-cv-985; *Teva Branded Pharmaceutical Prods. R&D Inc. et al. v. Perrigo Pharmaceuticals Co. et al.*, 1:13-cv-1441; *Unimed Pharmaceuticals LLC et al. v. Perrigo Company et al.*, 1:13-cv-236; *Teva Branded Pharmaceutical Prods. R&D Inc. et al. v. Perrigo Pharmaceuticals Co. et al.*, 1:12-cv-1101; *Cumberland Pharmaceuticals Inc. v. Paddock Laboratories LLC et al.*, 1:12-cv-619; *Cadence Pharmaceuticals Inc. et al. v. Exela Pharma Sciences LLC et al.*, 1:11-cv-733; *KV Pharmaceutical Co. et al. v. Perrigo Israel Pharmaceuticals et al.*, 1:10-cv-641; *Stiefel Laboratories Inc. et al. v. Perrigo Israel Pharmaceuticals Ltd. et al.*, 1:10-cv-592; *Schering-Plough Healthcare Prods., Inc v. Perrigo Company*, 1:09-cv-906; *Stiefel Research Australia Pty Ltd v. Perrigo Company et al.*, 1:09-cv-758; *Stiefel Laboratories Inc. et al. v. Cobrek Pharmaceuticals Inc. et al.*, 1:09-cv-167.

20. Upon information and belief, Perrigo's business model for its generic drugs is in large part predicated upon participating in a significant amount of litigation under the framework

of the Hatch-Waxman Act. Upon information and belief, the largest number of Hatch-Waxman cases have historically been filed each year in this district.

21. Upon information and belief, Perrigo, as a frequent ANDA filer, appears in front of this Court with regularity for the purpose of getting its generic drugs on the market, and when that litigation concludes favorably for Perrigo, those generic drugs are distributed to and used by Delaware residents through a distribution network that has been established for that purpose.

22. Upon information and belief, Perrigo is part of a corporate family that includes at least fifteen Delaware entities, including Defendant Perrigo New York, Inc., which reside in Delaware for patent venue purposes. Upon information and belief, the Perrigo corporate family as a whole relies on Delaware for its successful business operations.

23. Upon information and belief, Perrigo Company works in concert with its subsidiaries Perrigo Israel and Perrigo New York, Inc. to sell, market, and distribute its generic drugs in the United States, including in this district.

24. Venue is proper in this district under 28 U.S.C. § 1400(b) because Perrigo “committed an act of infringement” in this district and has a “regular place and established place of business” in this district. Perrigo submitted an ANDA leading to FDA approval of its generic halobetasol propionate lotion, 0.05% and, having received approval, will manufacture, sell, offer to sell, and/or import its generic halobetasol propionate lotion, 0.05% throughout the United States, including in this district. Perrigo also has a “regular and established place of business” in this district because of its pattern of litigation behavior, which largely takes place in this district and is directed to obtaining approval for the manufacture of and distribution of drugs to Delaware residents through established channels in this district.

BACKGROUND

The FDA Marketing Approval Process

25. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the FDA follows when considering the approval of applications for both brand-name and generic drugs.

26. Under the Hatch-Waxman Amendments, an applicant seeking to market a new brand-name drug must prepare a New Drug Application (“NDA”) for consideration by the FDA. *See* 21 U.S.C. § 355.

27. An NDA must include, among other things, the patent number of any patent that claims the drug or a method of using such drug, for which the applicant submitted the NDA and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1) and (c)(2); 21 C.F.R. §§ 314.53(b) and (c)(2).

28. Upon approval of the NDA, the FDA publishes patent information for the approved drug in its publication, *Approved Drug Products with Therapeutic Equivalence Evaluation* (“Orange Book”). *See* 21 U.S.C. § 355(j)(7)(A)(iii).

29. A pharmaceutical company may seek to market a generic version of the innovator’s brand drug by submitting an Abbreviated New Drug Application (“ANDA”) under 21 U.S.C. § 355(j). The generic company may then rely on the studies the innovator includes in its NDA.

Sun’s Ultravate® Product

30. On November 6, 2015, the FDA approved Sun’s NDA for Ultravate® (halobetasol propionate) Lotion, NDA No. 208183. Sun began marketing Ultravate® shortly after that approval.

31. Ultravate® is a corticosteroid indicated for the treatment of plaque psoriasis in patients 18 years of age or older. Psoriasis is a systemic inflammatory disease of immune dysfunction that affects an estimated 2%-3% of the U.S. population.

Plaintiffs' Patent Covering Ultravate®

32. The United States Patent & Trademark Office ("PTO") legally issued the '028 Patent, titled "Topical Steroid Composition And Method" on February 24, 2015. MiCal owns the '028 Patent, which lists Keith Johnson and Karl Popp as its inventors. The invention provides a storage stable topical lotion which includes a halobetasol material comprising halobetasol or its pharmaceutically acceptable salts, esters, and solvates; and a pharmaceutically acceptable carrier which includes one or more fatty alcohols and/or one or more alkoxyated fatty alcohols, one or more polyol humectants, and diisopropyl adipate. The invention also provides processes for preparing such topical lotion composition and methods for treating corticosteroid responsive dermatosis, including plaque psoriasis with such topical lotion composition.

COUNT I

(Infringement of the '028 Patent Under 35 U.S.C. § 271(e)(2)(A) by Perrigo's Proposed Generic Halobetasol Propionate Lotion, 0.05%)

33. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

34. Perrigo submitted ANDA No. 211464 to the FDA under section 505(j) of the US Federal Food, Drug, and Cosmetic Act ("FDCA") to obtain approval to engage in the manufacture, use or sale throughout the United States, of Perrigo's proposed generic halobetasol propionate lotion, 0.05% prior to the expiration of the '028 Patent. By submitting ANDA No. 211464, Perrigo has committed an act of infringement of the '028 Patent under 35 U.S.C. § 271(e)(2)(A).

35. The commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo's proposed generic halobetasol propionate lotion, 0.05% prior to the expiration of the '028 Patent will constitute an act of infringement of the '028 Patent.

36. On information and belief, Perrigo became aware of the '028 Patent no later than the date on which that patent was listed in the Orange Book.

37. On information and belief, Perrigo knows or is willfully blind to the fact that its commercial manufacture, use, offer for sale, sale, and/or importation of their proposed generic halobetasol propionate lotion, 0.05% will actively induce and contribute to the actual infringement of the '028 Patent.

38. On information and belief, Perrigo knows or is willfully blind to the fact that Perrigo's proposed generic halobetasol propionate lotion, 0.05% will be especially made for or especially adapted for use in infringement of the '028 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic halobetasol propionate lotion, 0.05% will actively contribute to the actual infringement of the '028 Patent.

COUNT II

(Declaratory Judgement of Infringement of the '028 Patent Under 35 U.S.C. § 271(a) by Perrigo's Generic Halobetasol Propionate Lotion, 0.05%)

39. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

40. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

41. An actual case or controversy between Plaintiffs and Perrigo exists such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution.

42. Perrigo has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell and/or import its generic halobetasol propionate lotion, 0.05%.

43. Perrigo's recent actions indicate that it does not intend to change its course of conduct.

44. Any manufacture, use, offer for sale, sale and/or importation of Perrigo's generic Halobetasol Propionate Lotion, 0.05% prior to the expiration of the '028 Patent will constitute direct infringement of at least claim 1 of the '028 Patent.

45. Plaintiffs are entitled to a declaratory judgment that any manufacture, use, offer for sale, sale and/or importation of the generic halobetasol propionate lotion, 0.05% by Perrigo prior to the expiration of the '028 Patent will constitute direct infringement of said patent.

46. On information and belief, despite having actual notice of the '028 patent, Perrigo continues to willfully, wantonly, and deliberately prepare to infringe the '028 Patent in disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT III

(Declaratory Judgment of Infringement of the '028 Patent Under 35 U.S.C. § 271(b) and (c) by Perrigo)

47. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

48. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

49. An actual case or controversy between Plaintiffs and Perrigo exists such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution.

50. Perrigo has actual knowledge of the '028 Patent.

51. On information and belief, Perrigo became aware of the '028 Patent no later than the date on which that patent was listed in the Orange Book.

52. On information and belief, Perrigo has acted with full knowledge of the '028 Patent and without a reasonable basis for believing that Perrigo would not be liable for actively inducing or contributing to the infringement of the '028 Patent.

53. The commercial manufacture, use, sale, offer for sale, and/or importation of Perrigo's generic halobetasol propionate lotion, 0.05% will induce the actual infringement of the '028 Patent.

54. On information and belief, Perrigo knows or is willfully blind to the fact that their commercial manufacture, use, sale, offer for sale, and/or importation of its generic halobetasol propionate lotion, 0.05% will actively induce the actual infringement of the '028 Patent.

55. On information and belief, Perrigo will encourage another's infringement of the '028 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of their generic halobetasol propionate lotion, 0.05%, which is covered by the claims of the '028 Patent.

56. Perrigo's acts of infringement will be done with knowledge of the '028 Patent and with the intent to encourage infringement.

57. The foregoing actions by Perrigo will constitute active inducement of infringement of the '028 Patent.

58. On information and belief, Perrigo knows or is willfully blind to the fact that Perrigo's proposed halobetasol propionate lotion, 0.05% will be especially made or especially adapted for use in an infringement of the '028 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

59. The commercial manufacture, use, sale, offer for sale, and/or importation of Perrigo's halobetasol propionate lotion, 0.05% will contribute to the actual infringement of the '028 Patent.

60. On information and belief, Perrigo knows or is willfully blind to the fact that Perrigo's offer for sale, sale and/or importation of its generic halobetasol propionate lotion, 0.05% will contribute to the actual infringement of the '028 Patent.

61. The foregoing actions by Perrigo will constitute contributory infringement of the '028 Patent.

62. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo's generic halobetasol propionate lotion, 0.05% by Perrigo will induce and/or contribute to infringement of the '028 Patent.

63. The commercial manufacture, use, offer for sale, sale and/or importation of Perrigo's generic halobetasol propionate lotion, 0.05%, which will actively induce and/or contribute to infringement of the '028 Patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

64. Unless Perrigo is enjoined from actively inducing and contributing to the infringement of the '028 Patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

65. On information and belief, despite having actual notice of the '028 Patent, Perrigo will willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '028 Patent in disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

PRAYER FOR RELIEF

Plaintiffs respectfully pray for the following relief:

(a) That judgment be entered that Perrigo has infringed the '028 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211464 under the FDCA, and that the commercial manufacture, use, offer for sale, sale and/or importation of Perrigo's proposed generic halobetasol propionate lotion, 0.05% prior to patent expiry will constitute an act of infringement of the '028 Patent;

(b) That a declaration be issued under 28 U.S.C. § 2201 that if Perrigo, Perrigo's officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in concert or participation with Perrigo or acting on Perrigo's behalf, engage in the commercial manufacture, use, offer for sale, sale and/or importation of Perrigo's generic halobetasol propionate lotion, 0.05% prior to the expiration of the '028 Patent, it will constitute infringement of said patent;

(c) That an injunction be issued under 35 U.S.C. § 283 permanently enjoining Perrigo, Perrigo's officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in concert or participation with Perrigo or acting on Perrigo's behalf, from engaging in the commercial manufacture, use, offer to sale or sale within the United States, or importation into the United States, of any drug product covered by the '028 Patent, including but not limited to halobetasol propionate lotion, 0.05%, prior to the expiration date of such patent, including any extensions or exclusivities;

(d) That damages or other monetary relief be awarded to Perrigo under 35 U.S.C. §§ 271(a), (b), (c) and/or 35 U.S.C. § 284 as appropriate;

(e) That this is an exceptional case under 35 U.S.C. § 285 and that Plaintiffs be awarded reasonable attorneys' fees and costs; and

(f) That this Court award such other and further relief as it may deem just and proper.

Dated: May 9, 2018

Respectfully submitted,

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